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| EXAMINER | |
|---|---|
| KIM, TAEYOON | |
| ART UNIT | PAPER NUMBER |
| 1651 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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| 3 MONTHS | 02/08/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/759,033 | REISNER ET AL. | |
| | Examiner | Art Unit | |
| | Taeyoon Kim | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *10,11,13-17,19-23 and 36-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12,18 and 24-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/12/06, 6/26/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-57 are pending.

### *Election/Restrictions*

Applicant's election without traverse of Group I (claims 1-34) in the reply filed on Aug. 7, 2006, and an elected species of hepatic disorder in the reply filed on Dec. 21, 2006 is acknowledged.

Claims 10, 11, 13-17, 19-23* and 36-57* have been withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-9, 12, 18 and 24-35* have been considered on the merits. (*These claims numbers have been renumbered. See below)

### *Claim Objections*

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. There are two claims of 21 in the current application. Misnumbered claims 21 (the second claim 21) through claim 56 have been renumbered as claims 22-57.

Claim 23, 26-28 and 30-35 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Because of renumbering, the dependent claims (i.e. claims 23, 24, 26-28, 30-35, 37-43, 45-57) need to be corrected.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 12, 18 and 24-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37-84 of copending Application No. 11/037025. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications disclose transplanting hepatic tissue derived from a porcine liver along with administering an immunosuppressive drug for hepatic disorder.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 12, 18 and 24-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 1 and its dependents is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is vague and indefinite what the subject matter "not substantially expressing" points out.

The term "associated with" in claim 1 and its dependents does not clearly point out what the subject matter the claims are intended to claim. It is not clear whether a disorder is caused by pathological organ, tissue physiology or morphology, or a disorder caused any pathological organ, etc.

The term "morphology" in claim 1 and its dependents does not clearly point out what the subject matter the claims are intended to claim. It is vague and indefinite because it is not clearly pointed out what the term is intended to claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 12, 18 and 24-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant does not describe a treatment of a "disorder" (even a hepatic disease) in any way that would suggest applicant possessed this invention at the time of filing. Applicant has some hypothetical examples but no indication of actual invention. Further applicant generically claims "treating a disorder" (or even specifically treating a hepatic disease) but the specification does not contain an adequate description for the entire scope of this limitation and thus the claims. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568,43 USPQ2d at 1406.

Claims 1-9, 12, 18 and 24-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

Applicant has not enabled the treatment of any or all disorders or even hepatic diseases. Applicant has not demonstrated that the instant method actually treats any disease nor demonstrated how the method of treatment they claimed can be extrapolated into the actual treatment of any disorder including hepatic disorders. Therefore, it would require undue experimentation to determine what kind of hepatic disorders could even potentially be treated by the method of current invention. The mere transplantation of hepatic tissue with an immune-suppressing regimen would not be expected to reverse or even treat any hepatic disease. Even further, applicant has disclosed in the specification that "treating" the disorder includes curing of the disorder

(p. 23, lines 21-22). However, there are currently many incurable hepatic disorders including primary biliary cirrhosis (PBC) according to an article entitled "what is primary biliary cirrhosis?" (http://www.cumc.columbia.edu/dept/gi/PBC.html). It is not readily apparent whether the method of treatment of the current invention would be able to cure PBC.

The claim is very broad and inclusive of liver diseases generally. The breadth of the claim exacerbates the complex nature of the subject matter to which the present claim is directed. The claim is extremely broad due to the vast number of possible hepatic disorders.

Furthermore, the lack of significant guidance from the present specification or prior art with regard to the actual treatment of all hepatic disorder in a mammal, including a human subject, with the claimed method makes practicing the claimed invention unpredictable.

Absent a reasonable *a priori* expectation of success for using fetal tissue transplantation to treat any particular type of liver disease, one skilled in the art would have to extensively test many various hepatic disorders. Since each prospective embodiment, and indeed future embodiments as the art progresses, would have to be empirically tested, and those which initially failed tested further, an undue amount of experimentation would be required to practice the invention as its is claimed in its current scope, because the specification provides inadequate guidance to do otherwise.

Given that there is no example of actual "hepatic disease" treatment and no clear correlation to other successful fetal transplant treatments of disease, the instant invention cannot be considered enabled.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-9, 12, 18 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bravery et al. (WO/2000/39294).

Claims 1, 7-9, 12, 18 and 24 are drawn to a method of treating a disorder comprising transplanting into a subject a mammalian organ/tissue which does not express a molecule capable of stimulating/enhancing immune response (claim 1); a limitation to the molecule capable of stimulating/enhancing immune response being a lymphocyte co-receptor or its ligand (claim 7); a limitation to the lymphocyte co-receptor or its ligand being CD40 (claim 8); a limitation to the step of selecting mammalian organ/tissue being via RT-PCR analysis (claim 9); a limitation to the organ being a hepatic organ (claim 12); a limitation to the disorder being a hepatic disorder and the organ being a hepatic organ (claim 18); a limitation to mammalian organ being a porcine organ (claim 24).

Bravery et al. teach a method of treating a disorder by using a graftable mammal, preferably porcine, cells, tissues or organs comprising cells which are genetically

modified to render them incapable of expressing CD40 antigen, and their use to prevent or inhibit chronic xenograft rejection in a recipient mammal receiving a xenograft (see Abstract). Bravery et al. also teach deletion of CD40 expression in transgenic pigs/piglets is analyzed by RT-PCR (see p.7, second paragraph). Although Bravery et al. particularly disclose the method of treating a disorder, xenotransplantation of organ from CD40-deficient piglets would have inherently carried out the method of treating a disorder.

Thus, the reference anticipates the claimed subject matter.

Claims 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Smikodub et al. (US 5,811,089).

Claims 25-28 are drawn to a method of treating a disorder comprising transplanting into a subject a human organ/tissue at a stage of differentiation corresponding to 5-16 weeks of gestation (claim 25); a limitation to the stage being 6-15 weeks of gestation (claim 26); a limitation to the stage being 7-14 weeks of gestation (claim 27); a limitation to the stage being 7-8 weeks of gestation (claim 28).

Smikodub et al. teach a method of treating acquired immune deficiency syndrome (HIV infection) by administering hemopoietic liver and/or spleen cells of a human embryo (see Abstract). Smikodub et al. also teach the human embryo being at 5-8 weeks of gestation (see column 4, line 19).

M.P.E.P. §2131.02 states, "When the prior art discloses a range which touches or overlaps the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to

anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, and the reference teaches a broad range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. See, e.g., Atofina v. Great Lakes Chem. Corp, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) wherein the court held that a reference temperature range of 100-500 degrees C did not describe the claimed range of 330-450 degrees C with sufficient specificity to be anticipatory. Further, while there was a slight overlap between the reference's preferred range (150-350 degrees C) and the claimed range, that overlap was not sufficient for anticipation. "[T]he disclosure of a range is no more a disclosure of the end points of the range than it is each of the intermediate points." Id. at 1000, 78 USPQ2d at 1424. Any evidence of unexpected results within the narrow range< may also render the claims unobvious. The question of "sufficient specificity" is similar to that of "clearly envisaging" a species from a generic teaching.

Since the teaching of 5-8 weeks of gestation clearly within the range of 6-15 weeks and 7-14 week of gestation limited in claims 26 and 27, the anticipation is clearly held.

Thus, the reference anticipates the claimed subject matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bravery et al. (supra) in view of Cottens et al. (US 6,274,629).

Claims 1-6 are drawn to a method of treating a disorder comprising transplanting into a subject a mammalian organ/tissue which does not express a molecule capable of stimulating/enhancing immune response (claim 1); a limitation to the method further comprising treating with immunosuppressive regimen (claim 2); a limitation to the immunosuppressive regimen being by administering an immunosuppressant drug (claim 3); a limitation to the immunosuppressant drug being capable of blocking binding of a lymphocyte co-receptor with its ligand (claim 4); a limitation to the immunosuppressant

drug being CTLA4-Ig (claim 5); a limitation to the duration of administering an immunosuppressant drug being 1-20 days (claim 6).

Bravery et al. anticipate the limitation of claim 1 and hence render obvious (see above).

Although Bravery et al. teach the use of a modern immunosuppressant drug in organ transplantation, Bravery et al. do not teach the use of CTLA4-Ig.

Cottens et al. teach the use of CTLA4-Ig or an immunosuppressive monoclonal antibody against CD40 (see column 5, lines 27-32).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the immunosuppressant compounds in the method of xenotransplantation using a CD40-deficient porcine organ taught by Bravery et al.

The skilled artisan would have been motivated to make such a modification because xenotransplantation even with CD40-deficient organ would trigger immune response, and therefore, immunosuppressive compounds such as those taught by Cottens et al. would be beneficial to prevent rejection of xenografts.

The person of ordinary skill in the art would have had a reasonable expectation of success in using immunosuppressive compounds such as CTLA4-Ig because these compounds have been successfully used for suppress immune response in transplantation.

Bravery et al. in view of Cottens et al. do not teach the range of duration of for administration of immunosuppressant drug, however, it would therefore have been

obvious for the person of ordinary skill in the art at the time the invention was made to optimize the duration of administering the drug to efficiently suppress immune response upon xenograft transplantation. See M.P.E.P. §2144.05.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claims 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (US 2001/0049827).

Claims 29-35 are drawn to a method of treating a disorder comprising transplanting into a subject a porcine organ/tissue at a stage of differentiation corresponding to 20-63 days of gestation (claim 29); a limitation to the stage being 20-56 days of gestation (claim 30); a limitation to the stage being 20-42 days of gestation (claim 31); a limitation to the stage being 20-35 days of gestation (claim 32); a limitation to the stage being 20-28 days of gestation (claim 33); a limitation to the stage being 24-28 days of gestation (claim 34); a limitation to the stage being 27-28 days of gestation (claim 35).

Hunter et al. teach a method for treatment of Parkinson's disease and islet cells for treatment of islet insufficiency-related diseases using porcine fetal neuronal cells (see Abstract).

Hunter et al. do not teach a specific stage of gestation of porcine organ/tissue/cells. However, it would have been obvious at the time of invention was made to optimize the gestational age of the xenograft as at the time of invention was made it was notoriously old and well known that embryonic cells of different age varied

in their development and differentiation and subsequently in their ability to grow in situ upon transplantation. Given the knowledge, the selection of specific days of gestation of porcine organ would have been a routine matter of optimization on the part of the artisan of ordinary skill. A holding of obviousness over the cited claims is therefore clearly required. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382.; See also M.P.E.P. § 2144.05

Furthermore it is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re* Aller, Lacey, and Haft, 105 USPQ 233 (CCPA 1955): Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. *In re* Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931,24 USPQ 52; *In re* Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. *In re* Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; *In re* Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the

capabilities of one skilled in the art. *In re* Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; *In re* Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; *In re* Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re* Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11,57 USPQ 136. (Emphasis added). With regards to determining experimental parameters, such as time in culture, the court has held that "[d]iscovery of optimum value of result effective variable in known process is ordinarily within skill of art (In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980)).

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim
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Art Unit 1651

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